IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

No. 5:13 CV 868

BENNIE EVANS, Plaintiff, vs. KENNETH RICH, M.D., CAPITAL NEUROSURGERY, INC., & ANULEX TECHNOLOGIES, INC., Defendants.	)	NOTICE OF REMOVAL 28 U.S.C. §§ 1331, 1441, and 1446 Wilson County Superior Court State of North Carolina 13 CVS 1763

TO: THE JUDGES OF THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA,
WESTERN DIVISION

Anulex Technologies, Inc., ("Anulex"), through its counsel, hereby files this Notice of Removal to remove the above-captioned case from the General Court of Justice, Superior Court Division, Wilson County, North Carolina, to the United States District Court for the Eastern District of North Carolina pursuant to 28 U.S.C. §§ 1331 and 1441. Pursuant to 28 U.S.C. § 1446(a) a copy of the entire state court file is attached as Exhibit 1, and includes all pleadings served or filed in this action as of the date of this notice.

In support of this notice of removal, Anulex states the following:

1. Bennie Evans ("Plaintiff") commenced this action by filing a Complaint on November 14, 2013, in the General Court of Justice, Superior Court Division, Wilson County, North Carolina, and the case was docketed as 13-CVS-1763.

2. Anulex received a copy of the Summons and Complaint by Certified Mail on

November 20, 2013.[1] As such, this removal is timely under 28 U.S.C. § 1446(b).

3. Removal to the United States District Court for the Eastern District of North Carolina is appropriate pursuant to 28 U.S.C. §§ 113(a) and 1441(a) because the Eastern District of North Carolina is the federal judicial district and division embracing the Superior Court of Wilson County, North Carolina.

4. Plaintiff's Complaint asserts claims against Anulex sounding in negligent misrepresentation, fraud, unfair and deceptive trade practices, and breach of the implied warranty of merchantability and/or of fitness for a particular purpose. The factual allegation underpinning each of Plaintiff's claims against Anulex is that Anulex promoted the "'Xclose Plus Tissue Repair System [as] provid[ing] a uniquely simple method for treating the compromised soft tissue of the annulus fibrosus' in violation of the Food and Drug Administration's ("FDA") prohibition against promoting investigational devices prior to FDA approval." (Compl. ¶ 6.) Plaintiff alleges that his physician used two Xclose suture devices to repair his annulus fibrosus in connection with a discectomy procedure performed on November 15, 2010. (Compl. ¶ 4.)

5. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331, federal question jurisdiction.

6. Under the substantial federal question doctrine, a case can arise under federal law even where the claims asserted in the case find their origin in state law. *Gunn v. Minton*, 133 S. Ct. 1059, 1064 (2013). "[F]ederal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Id.* at 1065.

[1] By filing this Notice of Removal, Anulex specifically does not waive its right to file any Rule 12 motions, including but not limited to a motion based on the fact that Anulex has not been properly served in this matter.

"Where all four of these requirements are met, . . . jurisdiction is proper because there is a serious federal interest in claiming the advantages thought to be inherent in a federal forum, which can be vindicated without disrupting Congress's intended division of labor between state and federal courts." *Id.* (internal quotation marks omitted).

7. The FDA first cleared the Xclose device through the 510(k) process and classified it as a Class II surgical suture under 21 CFR § 878.5000 on September 1, 2006. The FDA cleared the Xclose again on June 12, 2009 to accommodate a change in material, although the Xclose remained classified in the same manner as before. The Xclose's FDA clearance states that it is "indicated for use in soft tissue approximation for procedures such as general and orthopedic surgery."

8. Immediately upon its clearance in 2006, Anulex began distributing the Xclose and marketing it for use in approximating the annulus fibrosus as an adjunct to the discectomy procedure. The annulus fibrosus is a type of soft tissue and a discectomy is a type of orthopedic surgery. Since its clearance in 2006, over 16,000 patients have had the Xclose implanted to approximate the annulus fibrosus following discectomy without evidence of new risks introduced by use of the device.

9. In March 2007, Anulex initiated enrollment into a clinical study of the Xclose device when used to approximate the annulus fibrosus as an adjunct to the discectomy procedure. Each of the 34 clinical sites at which the study took place received institutional review board (IRB) approval and patients gave their consent to the procedure prior to enrollment. Anulex, in full transparency, posted the study on the government's website; clinical trials.gov. Enrollment was completed for the clinical study in August 2009, over one year before Plaintiff underwent his discectomy procedure. Each of the 34 clinical sites' IRBs approved the study and all

concurred that FDA approval was not required for the study because the use of the Xclose to approximate the annulus fibrosus as an adjunct to the discectomy procedure was contemplated by its cleared indication statement.

10. Given the FDA's clearance of the Xclose for soft tissue approximation for procedures such as general and orthopedic surgery, the Federal Food, Drug, and Cosmetic Act ("FDCA") and regulations and guidance under the FDCA must be applied to the facts of this case to determine whether the Xclose was cleared for the use at issue at the time of Plaintiff's procedure. *See* 21 CFR § 807.81(a)(3)(ii) (requiring a new 510(k) application for "a major change or modification in the intended use of the device"); FDA, Deciding When to Submit a 510(k) at 9 (1997) (noting that "[a]ny change in the indications for use that limits use within the currently cleared indication may occur without the submission of a 510(k)"); FDA, General/Specific Intended Use at 2-3 (1998) (providing guidance on when a specific indication for use will be substantially equivalent to a general indication for use and when a specific indication for use becomes a new intended use that requires submission of a PMA to establish safety and effectiveness); *see also* 21 CFR § 812.2(c) (noting that a cleared device that is used or investigated in accordance with the cleared indications for use is exempted from the investigational device regulations). Thus, whether Anulex is liable for negligent misrepresentation, fraud, unfair and deceptive trade practices, or breach of warranty by virtue of its promotional statements necessarily raises exclusively federal legal questions.

11. As of November 15, 2010, the time of Plaintiff's surgery, Anulex had been promoting the Xclose for annular repair, consistent with its cleared indication for use statement, for over four years. The FDA took issue with Anulex's promotional and investigational activities through a February 11, 2011 warning letter. Following the issuance of the warning

letter, Anulex disputed the FDA's interpretation of the Xclose's cleared indication statement and no federal court has found that Anulex's promotional or investigational activities violated the FDCA or adopted the FDA's interpretation of the Xclose's cleared indication statement. Thus, the federal issue concerning the scope of the Xclose's clearance is actually disputed here.

12. Whether the Xclose's cleared indication for use statement includes annular repair implicates sensitive determinations of federal regulatory law and agency policy that Congress intended to be made by a federal court. *See, e.g.*, 12 U.S.C. § 331(a), 333(a), 333(f) (allowing the government to prosecute or seek civil penalties against device sponsors in federal court for promoting a medical device outside of its clearance); 5 U.S.C. § 702 et seq. (providing for judicial review of federal agency actions in the courts of the United States); 21 U.S.C. § 360g(a)(8) (allowing a person adversely affected by an order finding a device not substantially equivalent to petition the D.C. Circuit Court of Appeals for review of that order). As such, the federal issue is substantial.

13. Plaintiff's Complaint does not present a typical product liability or consumer fraud lawsuit that the States have historically resolved. Instead, Plaintiff's Complaint raises issues with the scope of an FDA clearance and whether Anulex marketed the Xclose within that scope. Congress intended these issues to be resolved in federal court and there is no applicable state law that can be applied to resolve promotional and investigational issues. Thus, a federal forum may entertain this dispute without disturbing the balance between state and federal courts.

14. Although Plaintiff has not alleged a federal question claim against the other Defendants, *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001), this Court has supplemental jurisdiction over all other claims alleged in the Complaint. *See* 28 U.S.C. § 1367(a) ("[T]he district courts shall have supplemental jurisdiction over all other claims that

are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy . . . .").

15. The consent of the other Defendants to the removal of this action is not required because, on information and belief, they have not been served and/or their time to remove this action has not expired. 28 U.S.C. § 1446(b)(2)(A).

16. Concurrent with the filing of this Notice of Removal, Anulex is serving this Notice of Removal on all co-defendants and all counsel of record and filing a copy of the Notice of Removal with the Clerk of the General Court of Justice, Superior Court Division, Wilson County, North Carolina pursuant to 28 U.S.C. § 1446(d).

Respectfully submitted this 20th day of December, 2013.

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Attorneys for Defendant Anulex Technologies, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served the foregoing Notice of Removal by placing a copy of same in the United States Mail, first class postage prepaid, addressed as follows:

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This 20th Day of December, 2013.

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